APPENDIX A – TDL-220257

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE

TDL-220257

MEMORANDUM

DATE: February 25, 2022

FROM: Contracting Officer's Representatives (CORs)
Medicare Administrative Contractors, Center for Medicare

Director, Technology, Coding and Pricing Group
Center for Medicare

Director, Medicare Enrollment & Appeals Group
Center for Medicare

Director, Medicare Contractor Management Group
Center for Medicare

SUBJECT: Medicare Benefit Policy Classification and Payment for Continuous Glucose Monitors (CGMs)

TO: All Medicare Administrative Contractors (MACs)

This Technical Direction Letter (TDL) provides instructions to the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) regarding Medicare benefit policy classification and payment for continuous glucose monitors (CGMs). The Centers for Medicare & Medicaid Services (CMS) published a final rule on December 28, 2021 that addresses classification and payment for CGMs under the Medicare Part B benefit for durable medical equipment (DME). *See* 86 Fed. Reg. 73,860, 73,896–73,902 (Dec. 28, 2021) ("2021 final rule"). The 2021 final rule is effective on February 28, 2022, and thus applies to claims for a CGM monitor or receiver and/or its necessary supplies and accessories that are supplied to a Medicare beneficiary on or after February 28, 2022. This TDL is effective on February 28, 2022.

The 2021 final rule replaced a 2017 CMS Ruling, CMS-1682-R ("2017 Ruling"), regarding CGMs. Pursuant to this TDL, the DME MACs shall apply the coverage and payment provisions of the 2021 final rule to valid reimbursement claims and appeals for CGM monitors or receivers

and/or necessary supplies and accessories supplied prior to February 28, 2022. The 2021 final rule obviates the need for further application of the 2017 Ruling on CGMs, as CMS has determined that, in addition to therapeutic or non-adjunctive CGMs, non-therapeutic or adjunctive CGMs can also meet the Medicare definition of durable medical equipment (DME) at 42 C.F.R. § 414.402. Applying the coverage and payment provisions of the 2021 final rule to valid reimbursement claims and appeals for CGM monitors or receivers and/or necessary supplies and accessories supplied prior to February 28, 2022 will avoid expending administrative resources on further application of the 2017 Ruling on CGMs and additional appeals challenging application of the 2017 Ruling.

For valid claims and appeals covered by this TDL, both therapeutic or non-adjunctive CGMs and non-therapeutic or adjunctive CGMs shall be considered DME by the DME MACs pursuant to this TDL if the CGM's monitor or receiver satisfies the definition of DME in 42 C.F.R. § 414.202. This includes CGM monitors and receivers that are incorporated into insulin infusion pumps, which as the 2021 final rule indicates should not have been denied based on the 2017 Ruling in any event. If a specific CGM monitor or receiver is classified and covered as DME, or the CGM monitor or receiver is incorporated into an insulin infusion pump, then the CGM sensors and transmitters used in conjunction with the CGM monitor or receiver shall also fall under the DME benefit if they are determined to be supplies and accessories necessary for the effective use of the CGM. Coverage of a specific CGM monitor or receiver and/or its necessary supplies or accessories shall still also require a determination that the CGM is found to be medically reasonable and necessary for the diagnosis or treatment of an illness or injury for the beneficiary.

Pursuant to this TDL, if a therapeutic or non-adjunctive CGM is classified and covered as DME or the monitor or receiver is part of a covered insulin infusion pump and the CGM monitor or receiver is medically reasonable and necessary, then the CGM monitor or receiver and/or its necessary supplies and accessories shall be paid in accordance with the appropriate fee schedule amounts. If a non-therapeutic or adjunctive CGM is classified and covered as DME or the monitor or receiver is part of a covered insulin infusion pump and the CGM monitor or receiver is medically reasonable and necessary, then the CGM monitor or receiver and/or the supplies and accessories necessary for the effective use of the CGM monitor or receiver shall be paid in accordance with fee schedule amounts established in accordance with 42 C.F.R. § 414.238 and the fee schedule gap-filling instructions in section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

The DME MACs shall apply the direction in this TDL to CGM monitors or receivers and/or their necessary supplies and accessories supplied to a beneficiary before the February 28, 2022 effective date of the 2021 final rule where either (1) a valid reimbursement claim or valid appeal is pending as of February 28, 2022; or (2) the right to submit a valid reimbursement claim or file a valid appeal has not expired as of February 28, 2022.

More specifically, DME MACs shall apply the instructions in this TDL to valid CGM reimbursement claims and appeals: (1) that were open (i.e., non-final) as of February 28, 2022, if the timeframe to file a valid appeal has not expired before that date; or (2) that are submitted after February 28, 2022 for CGM monitors or receivers and/or their necessary supplies and accessories supplied before February 28, 2022, so long as the claim or appeal is submitted timely and in accordance with all procedural requirements. For example, if an initial determination on a CGM claim was issued before February 28, 2022, and the 120-day period for requesting redetermination has not expired before that date, then this TDL shall be applied to that claim.

However, this TDL shall not be applied to CGM reimbursement claims that were final and binding before February 28, 2022 and the right to file a valid appeal has expired before that date. For example, if an initial determination on a CGM claim was issued but the 120-day period for requesting redetermination has expired before February 28, 2022, then this TDL shall not be applied to that claim. In any event, CGM reimbursement claims for CGM monitors or receivers and/or their necessary supplies and accessories supplied on or after February 28, 2022 are covered directly by the 2021 final rule.

In order to conserve administrative resources and further the interests of administrative finality, this TDL shall not serve as a basis for reopening a determination or decision regarding a CGM reimbursement claim that was final and binding and no longer subject to appeal before the February 28, 2022 effective date of the 2021 final rule and this TDL.

DME MACs shall review CGM reimbursement claims previously denied and determine if the claims were valid or any appeal was valid as of the February 28, 2022 effective date of this TDL. For CGM claims appealed to the qualified independent contractor (QIC), the DME MACs shall provide a spreadsheet with a list of CGM claims pending at the QIC that might be eligible for coverage under the foregoing provisions of this TDL. CMS will issue instructions to the QIC for handling CGM claims and appeals pending at the QIC.

Provider Education

No national message will be distributed from CMS.

Local contractor messaging about this TDL is prohibited.

DME MAC Contract Numbers

Jurisdiction A ~ HHSM-500-2016-M0001Z
Jurisdiction B ~ HHSM-500-2015-M0030Z
Jurisdiction C ~ 75FCMC20C0025
Jurisdiction D ~ HHSM-500-2015-M0031Z

This Technical Direction Letter (TDL) is being issued to you as technical direction under your MAC contract and has been approved by your Contracting Officer's Representative (COR). This technical direction is not to be construed as a change or intent to change the scope of work under the contract and is to be acted upon only if sufficient funds are available. In this regard, your attention is directed to the clause of the General Provisions of your contract entitled Limitation of Funds, FAR 52.232-22 or Limitation of Cost, FAR 52.232-20 (as applicable). If the Contractor considers anything contained herein to be outside of the current scope of the contract, or contrary to any of its terms or conditions, the Contractor shall immediately notify the Contracting Officer in writing as to the specific discrepancies and any proposed corrective action.

Unless otherwise specified, contractors shall be in compliance with this TDL within 10 business days from its date of issuance.

Should you require further technical clarification, you may contact your COR. Contractual questions should be directed to your CMS Contracting Officer. Please copy the COR and Contracting Officer on all electronic and/or written correspondence in relation to this technical direction letter.

/s/
Pam Durbin, JA DME MAC COR
Lisa Laubach, JB DME MAC COR
Lisa Laubach, JC DME MAC COR
Pam Durbin, JD DME MAC COR

/s/
Jason Bennett
Jerry Mulcahy (he, him)
Larry Young

cc:
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